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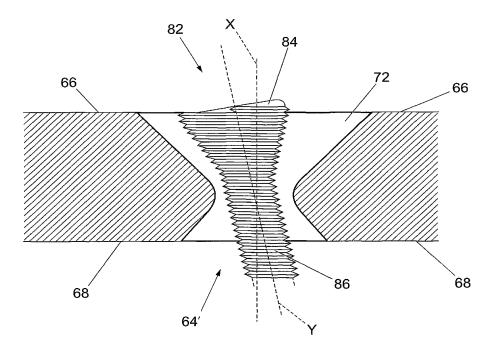
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(57) Abstract: A bone fixture apparatus such as plate or an intramedullary nail is disclosed, having a plug or other form of insert that engages screws passing through the nail or plate etc. The provision of the pliable insert allows the screw to be driven through the plate etc at a number of different angles. The application also concerns a pliable insert suitable for use with the plate or nail.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1	"Apparatus"
2	
3	This invention relates to apparatus for use in
4	supporting a fractured bone.
5	
6	It is known to support fractures in bones by rigid
7	bone fixture implants, common examples of which are
8	bone plates (commonly known as interlocking plates)
9	and intra-medullary (IM) nails.
LO	
L1	IM nails are inserted into the medullary canal of
12	the long bone, and are held in place by screws or
L3	other bone fasteners such as bolts or pins that are
L 4	driven laterally through the bone, typically at each
15	end of the nail. The screws etc also pass through
16	pre-drilled holes in the nail, thereby reducing or
17	preventing movement of the nail while the fracture
18	is healing. Holes must be bored through the bone in
19	order to insert the screws, and these must be
20	aligned with the pre-drilled holes in the ends of
21	the nail.
22	

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1 In order to drill the holes accurately through the 2 bone, a jig is commonly employed. The jig is attached to the protruding end of the nail after 3 4 insertion of the nail into the medullary canal, and typically extends parallel to the nail. 5 The jig has 6 pre-drilled holes that align with the holes in the 7 nail when the jig and the nail are properly 8 attached. 9 10 Interlocking bone plates are normally attached to 11 the exterior surface of bones using similar bone 12 fasteners such as bolts or screws. Like the IM 13 nail, the plate is arranged to span fractures and 14 the bone fasteners penetrate solid bone on opposing 15 sides of the fracture(s). 16 According to the present invention there is provided 17 18 a bone fixture apparatus having a pliable material 19 for engaging a fixing device. 20 21 The bone fixture apparatus can be attached to the outer or the inner surface of the bone. 22 23 the bone fixture apparatus comprises an intra-24 medullary nail. Alternatively, the bone fixture 25 apparatus comprises a bone plate (internal or external). Alternatively, the bone fixture 26 27 apparatus comprises a fracture brace. 28 29 Typically, the pliable material is capable of 30 plastic and/or elastic deformation, and can typically be a coating or insert. The pliable 31 material is typically softer that the material of 32

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the bone fixture apparatus, and has a lower Young's 1 The pliable material is preferably soft 2 modulus. enough to drill, mill or cut peroperatively, 3 typically under the influence of materials that are 4 harder than the pliable material. Typically such 5 harder materials are used for the fixing device 6 which is driven into the pliable material. 7 8 9 Optionally, the pliable material is a metal or a In certain embodiments the pliable 10 polvmer. material can be biodegradable. Biodegradable 11 variants are useful as the plate or nail typically 12 needs to be firmly attached to the bone without 13 allowing any movement only in the initial phase of 14 the fracture, so that it can take the loading 15 normally applied to the fractured area of bone 16 arising from everyday use. After the fracture has 17 healed, the implant is redundant and no longer needs 18 to bear any load. In some cases, the implant can be 19 20 left in place permanently, but in other cases, the implant can be removed from the bone, and 21 biodegradable inserts of the pliable material can 22 assist in such removal, as by the time the bone has 23 healed, the pliable material will have been eroded, 24 and the fixings can be more easily removed. 25 26 Biodegradable versions of the insert also lend 27 themselves very well to use with bone plates having 28 dynamization slots, as the screw can be driven 29 through the dynamization slot filled with the 30 pliable insert, and the degradation of the insert 31 over the succeeding weeks or months will then free 32

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the screw to move axially in the slot once the 1 initial healing has progressed to a suitable phase 2 where this movement is desirable, but retaining a 3 secure fixing of the screw, plate and bone when this 4 is necessary in the initial phase before healing of 5 the bone fracture. 6 7 The pliable material can be a non-metallic material 8 such as plastics material or an expanded carbon 9 complex. A further possibility is that the pliable 10 material is a naturally occurring (and preferably 11 bioabsorbable) material such as a collagen or 12 polypeptide construct. 13 14 The apparatus may have a hole to receive the fixing 15 device, and the pliable material may preferably be 16 located at or in the hole. Preferably, the pliable 17 material is positioned e.g. bonded on a surface 18 (typically the internal surfaces of an aperture or 19 bore) of at least a part of the bone fixture 20 Preferably, some pliable material is apparatus. 21 disposed in the region(s) of the bone fixture 22 apparatus around or within the hole(s). In some 23 embodiments in the form of hollow nails etc, the 24 pliable material can be inserted into a central 25 canal of the nail. 26 27 In some embodiments, the pliable material is 28 settable so that it changes phase (e.g. from paste, 29 gel or liquid to a solid) on the application of 30 pressure or heat, when exposed to a chemical 31

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catalyst, or after an interval of time. Optionally, 1 the settable material is a glue or a paste. 2 3 The pliable material is optionally self-expanding. 4 5 Optionally, the pliable material changes phase, e.g. from liquid to solid when it expands. 6 7 Optionally, the bone fixture apparatus has 8 predrilled holes to receive fixings. The holes can 9 be on different planes, and can be lateral holes or 10 in other planes. The holes can be filled or lined 11 with pliable material. Optionally, screws or other 12 13 bone fixings are inserted into the pliable material to form holes through the pliable material. 14 cases the bone fixture apparatus can have a window 15 through which the pliable material is exposed to the 16 fixing, and through which the screw etc can be 17 In certain cases the pliable material can 18 inserted. have a pilot hole pre-drilled therein to receive the 19 20 bone fixing. 21 Preferably, the fixing device is a screw or a bolt. 22 Threaded fixings are preferred, but non-threaded 23 fixings such as pins etc can be used. Preferably, 24 the fixing device is longer than the diameter of the 25 26 apparatus. 27 In some nails formed as a rolled tube, each hole has 28 a circumferentially opposite hole. Each hole (or 29 pair of opposite holes) can typically receive the 30 fixing device. Potentially, the pair of opposite 31 holes could form the ends of a generally cylindrical 32

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passage through a solid nail. The entire passage 1 could be filled with pliable material, or 2 alternatively the walls of the passage could be at 3 least partially lined with pliable material. 4 some embodiments the pliable material can comprise 5 at least one ring (preferably two rings) of e.g. 6 plastics material such as Nylon(TM) on the inner 7 diameter of (or within) at least one of the holes 8 (preferably each end of each hole has a respective 9 10 ring). 11 Optionally, the pliable material extends down the 12 full length of cannulated nails, although it is only 13 necessary for the pliable material to be located 14 where the fixing devices engage the bone fixture 15 apparatus; thus the pliable material and/or the 16 holes to engage the bone fixings could be anywhere 17 on the apparatus. 18 19 Optionally, the holes have parallel sides, but in 20 certain embodiments, the sides of the holes are 21 tapered. Bi-directionally tapered embodiments, 22 where the sides of the holes taper inwardly from 23 both the upper and lower surfaces of the bone fixing 24 apparatus to an apex, can be advantageous, as the 25 narrower width of the hole at the apex can serve to 26 27 hold the pliable material in position, without the need for an adhesive. The apex of the hole is 28 typically located just below the centre point of the 29 hole axis. The embodiments having bi-directional 30 tapering are typically used with a solid insert of 31

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pliable material which fills, or nearly fills the 1 2 hole. 3 Optionally, the pliable material is in the form of 4 an insert which has a compressible portion. 5 kind of insert is especially useful for use with 6 holes having a narrow portion. The compressible 7 portion can be compressed to fit through the narrow 8 portion of the hole. The compressible portion may 9 have legs divided by elongate slits. The slits are 10 typically wedge-shaped, and allow for the legs to be 11 pushed together to reduce the diameter of the 12 compressible portion. For example, before 13 compression, the legs may form part of a frusto-14 conical portion of the insert; thus the legs have a 15 partially radial extent. On compression, the legs 16 can be squeezed into a cylindrical shape to fit 17 through the narrow portion of the hole. 18 useful if the compressible portion is formed from a 19 resilient material, so that when the legs have 20 passed through the narrow portion of the hole, they 2.1 extend radially outwards again to hold the insert in 22 23 the hole. 24 Other embodiments of bone fixing apparatus have 25 These may be used 26 tapered frusto-conical holes. with inserts which fill the holes, or alternatively, 27 the hole walls may be lined with the pliable 28 material. 29 30

The holes in the bone fixing apparatus may be screw-

32 threaded and the pliable material may be in the form

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of an insert having corresponding threads; 1 2 alternatively, threads may be formed in the insert on screwing the insert into the threaded holes. 3 4 Optionally, the nail can be hollow and the entire 5 cross-section of the nail is filled with the pliable 6 material, at least in the areas where the screws 7 will engage the nail, e.g. at the ends. 8 Alternatively, the bone fixture apparatus can be 9 solid and the pliable material can comprise a hollow 10 sleeve or ring(s), or a solid plug inside a passage 11 through the bone fixture apparatus adapted to 12 receive the fixing screws. Another possibility is 13 14 that the pliable material lines the inside surface of a hollow bone fixture apparatus. 15 16 According to a further aspect of the present 17 invention, there is provided a method of supporting 18 a fractured bone, the method comprising the steps 19 of: attaching a bone fixture apparatus to the bone 20 and engaging at least one fixing device with the 21 bone, wherein the bone fixture apparatus is provided 22 with a pliable material and the fixing device is 23 engaged with the pliable material. 24 25 26 The bone fixture apparatus may comprise an intramedullary nail, and the method optionally includes 27 28 the step of inserting the intra-medullary nail into 29 the medullary cavity of the bone. Alternatively, the bone fixture apparatus may comprise a bone 30 31 plate. 32

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Preferably, the apparatus spans one or more 1 fractures in the bone, and the screws are driven 2 into the bone fixture apparatus on opposing sides of 3 4 the fracture(s). 5 The pliable material is typically attached to a part 6 of the bone fixture apparatus. 7 8 The fixing device may optionally be inserted through 9 at least one hole in the bone fixture apparatus; the 10 hole is typically at least lined and optionally 11 filled with pliable material. The pliable material 12 may be inserted into the hole either before or after 13 the bone fixture apparatus is attached to the bone. 14 15 16 A simple option is to fill the holes in the bone fixture apparatus with pliable material. A simple 17 ring of plastic material around the inside of each 18 hole would be sufficient, and in such cases the 19 inner diameter of the ring is preferably less than 20 the diameter of the shank of the screw. Another 21 possibility is to insert one or more sleeves or 22 23 cylinders of pliable material to span the gap(s) between holes in opposite sides of a hollow bone 24 fixture apparatus and is supported by the holes. 25 26 Typically, the pliable material acts to minimize 27 movement of the screw with respect to the bone 28 29 fixture apparatus. 30 Typically, inserting a screw displaces some of the 31 pliable material, which expands against a surface of 32

1	the bone fixture apparatus. This expansion force
2	helps to hold the screw stationary with respect to
3	the bone fixture apparatus. In such examples, the
4	pliable material is typically contained within a
5	containment area in the bone fixture apparatus, so
6	that when the pliable material expands it pushes
7	against the walls of the containment area and
8	increases the grip between the bone fixture
9	apparatus and the screw. In certain embodiments the
10	material can be self-expanding, and this can
11	increase the grip of the screw on the bone fixture
12	apparatus. In other embodiments of the invention,
13	the screw can cut threads in the pliable material
14	and this can help to hold the screw steady relative
15	to the bone fixture apparatus. Preferably the
16	pliable material is contained or received within the
17	hole that also accommodates the fixing device, and
18	the act of driving the fixing device through the
19	pliable material in the hole expands or deforms the
20	pliable material within the hole and holds the
21	fixing therein.
22	
23	According to a further aspect of the present
24	invention, there is provided the use of a pliable
25	material in co-operation with a bone fixture
26	apparatus in a method of supporting a bone fracture.
27	
28	According to a further aspect of the present
29	invention, there is provided a pliable insert for
30	engaging a fixing device for a bone fixture
31	apparatus.
32	

T	According to a further aspect of the present
2	invention, there is provided a bone fixing apparatus
3	having at least one hole, wherein the hole is
4	provided with a tapered inner surface.
5	
6	An embodiment of the invention will now be described
7	by way of example only and with reference to the
8	following drawings, in which:-
9	
10	Fig 1 shows a cross-sectional view of an intra-
11	medullary nail inside the medullary canal of a
12	broken bone;
13	Fig 2 shows a side view of an intra-medullary
14	nail attached to a jig;
15	Fig 3 shows a cross-sectional view of an intra-
16	medullary nail filled with a pliable material;
17	Fig 4 shows a cross-sectional view of the
18	apparatus of Fig 3 with a screw extending
19	through the nail;
20	Fig 5 shows a cross-sectional view of an intra-
21	medullary nail on the interior of which is an
22	annulus of pliable material;
23	Fig 6 shows the cross-sectional view of the
24	apparatus of Fig 5 with a screw extending
25	through the nail;
26	Fig 7 shows a cross-sectional view through a
27	solid nail in accordance with another
28	embodiment;
29	Fig 8 shows a cross-sectional view through a
30	solid nail in accordance with a further
31	embodiment;

1	Fig 9 shows a cross-sectional view through a
2	tubular nail in accordance with another
3	embodiment;
4	Fig 10 shows a cross-sectional view through a
5	tubular nail in accordance with a further
6	embodiment;
7	Fig 11 is a front view of a bone plate
8	according to the invention;
9	Fig 12 is an enlarged view of one of the holes
10	in the bone plate of Fig 11;
11	Fig 13 is a cross-sectional view taken along
12	the line A-B of Fig 12;
13	Fig 14 is a cross-sectional view of the bone
14	plate of Fig 11 having a pliable insert;
15	Fig 15 is a cross-sectional view of the bone
16	plate of Fig 11 having an alternative
17	embodiment of insert;
18	Fig 16 shows a cross-sectional view of the Fig
19	14 bone plate and pliable insert, having a
20	screw driven through the insert; and
21	Figs 17 and 18 show cross-sectional views of a
22	further embodiment of bone plate and insert.
23	
24	Referring now to the drawings, Fig 1 shows a bone
25	fixture apparatus in the form of an intra-medullary
26	nail 10, which is inserted inside the medullary
27	canal 12 of a broken bone 14. The broken bone 14
28	consists of two bone portions 16A and 16B. The
29	intra-medullary nail 10 extends substantially the
30	whole length of the medullary canal 12.
31	

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Fig 2 shows an intra-medullary nail 10 attached to a 1 jig 20 at one end. Both the nail 10 and the jig 2 have holes 18, 28 at each of their ends. Each hole 3 18 in the nail 10 is aligned with a respective hole 4 28 in the jig. A screw 26 is shown inserted through 5 a hole 18 in the nail 10, and a hole 28 in the jig 6 7 20. 8 One embodiment of the invention is illustrated in 9 10 Figs 3 and 4. 11 Fig 3 shows a hollow intra-medullary nail 10 of the 12 rolled tube type, which has lateral holes 18 aligned 13 at the same axial position on each side at the end 14 of the nail 10. The nail 10 is entirely filled with 15 a pliable material comprising a cylindrical insert 16 30 of polyethylene, which is inserted into the end 17 of the nail 10. 18 19 In use, the nail 10 is inserted into the medullary 20 canal of the bone portions 16A, 16B to be aligned. 21 The cylinder 30 of pliable material is inserted into 22 the nail 10 either before or after the nail 10 is 23 inserted into the medullary canal. The nail 10 is 24 then optionally attached at one end to a jig 20. At 25 least one screw 26 is driven into the bone on each 26 27 side of the break, at positions aligned with holes in the jig 20 and holes 18 the nail 10. The screws 28 26 pass through the holes 28 in the jig 20 and the 29 holes 18 in the nail 10, and engage the cylinder 30 30 of pliable material. The screw threads of screws 26 31

cut into the pliable material 30 as the screws are

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driven into it, thereby ensuring a firm grip of the 1 screw by the cylinder 30. The pliable material of 2 the cylinder 30 is also displaced radially outwards 3 and expands against the inside surface of the nail 4 10, thereby pressing the cylinder 30 against the 5 nail 10. The increased grip between the screw 26 6 and the cylinder 30 and between the cylinder 30 and 7 the nail 10 helps to keep the screws 26 stationary 8 with respect to the nail 10, thereby preventing or 9 restraining movement of the nail in the bone 16 10 11 which can disrupt the healing process. 12 13 It should be understood that the use of the jig is not essential for the working of this invention; it 14 is merely a useful tool to help to locate the holes 15 for the screws in alignment with the holes in the 16 nail 10. 17 18 Fig 4 shows the apparatus of Fig 3, with a screw 26 19 inserted through the holes 18 in the nail 10, and 20 through the cylinder 30. The pliable material of 21 the cylinder 30 has been squeezed outwards against 22 the inner surface of the nail 10 by the movement of 23 the screw 26, and exerts a force on the inside 24 surface of the nail 10 to keep the nail 10 in place. 25 26 An alternative embodiment of the invention is 27 described in Figs 5 and 6. This embodiment is 28 similar to that of Figs 3 and 4, except that the 29 pliable material is in the form of a liner or sleeve 30 32 that lines the inside surface of the nail 10 as 31

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shown in Fig 5, instead of filling the entire cross-1 2 section. 3 In use, the nail 10 is inserted into the medullary 4 canal as before. A hollow sleeve 32 of pliable 5 material is inserted into the nail 10 either before 6 or after the nail 10 is placed into the canal. 7 nail 10 is then attached at one end to a jig 20. 8 least one screw 26 is driven into the bone on each 9 side of the break at positions aligned with holes 28 10 in the jig 20 and holes 18 in the nail 10. Screws 11 26 are inserted through the hole 28 in the jig 20 12 and the hole 18 in the nail 10, and the screws 26 13 cut threads into the cylinder 32 of pliable 14 material, which helps to keep the screw 26 and the 15 intra-medullary nail 10 firmly connected with 16 reduced scope for movement of the nail 10 in the 17 bone during the healing process. 18 19 Fig 6 shows the embodiment of Fig 5 with a screw 20 inserted through the nail 10 and through the 21 cylinder 32 of pliable material. 22 23 The purpose of the pliable material is to hold the 24 screw in position and any shape/amount/type of 25 pliable material that achieves this function can be 26 used. It is generally useful if a part of the 27 pliable material forms, covers or surrounds a screw-28 receiving hole in the intra-medullary nail so that 29 the screw self-taps into it, forming its own threads 30 or hole in the pliable material. It is advantageous 31 but not necessary for the pliable material to be 32

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pressed against the nail, through either 1 displacement by the screw, and/or the pliable 2 material itself being self-expanding. 3 4 Figs 7 and 8 show how the invention can be applied 5 to a solid nail 50, which has a lateral bore 58 to 6 The bore 58 is lined with a sleeve receive a screw. 7 52 in the fig 7 embodiment that is formed from 8 pliable material (in this case the pliable material 9 is a polyamide). The sleeve 52 is deformed by the 10 screw threads as the screw penetrates the bore, and 11 this enhances the grip between the nail and the 12 The sleeve 52 can be replaced by one or more 13 annular rings 54 that can usefully be positioned at 14 opposite ends of the bore 58 as shown in the Fig 8 15 embodiment. 16 17 The annular rings 54 or the sleeve 52 can be used in 18 a tubular nail 10 as shown in Fig 9 and Fig 10. 19 It is not important which particular pliable 20 material is used; suitable materials include metals, 2.1 polymers (absorbable/non-absorbable), non-metallic 22 materials (e.g. carbon complexes) and naturally 23 occurring materials (e.g. collagen constructs). 24 25 It could be advantageous for the patient if only 26 small quantities of pliable material are used, so as 27 to keep the amount of foreign agents in his body to 28 Typically pliable materials that are 29 a minimum. biodegradable are preferred. 30 31

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A further alternative embodiment of the invention is 1 shown in Figs 11 to 14. Fig 11 shows a bone plate 2 60 which has a series of oval holes 62 and circular 3 holes 64 along its length; each hole extends through 4 5 the plate from an upper surface 66 of the plate to a 6 lower surface 68. One of the circular holes 64' is shown in more detail in Figs 12 and 13. 7 8 As best seen in Fig 13, the hole 64' has walls 65 9 which are tapered so that they are inclined relative 10 to each other and to the upper and lower surfaces 11 66, 68 of the bone plate. The hole 64' also has a 12 13 central axis X. 14 The wall 65 of the hole 64' inclines radially 15 16 inwardly towards the hole axis X from the top surface 66 to an apex 70, from where the wall 65 17 18 inclines radially outwards to the lower surface 68. The apex 70 is located slightly below the midpoint 19 of the hole 64'. The cross-section of the hole 64' 20 thus generally resembles an hourglass. 21 22 Referring now to Fig 14, a pliable insert 72 also 23 having the form of an hourglass is shown inserted 24 into the hole 64'. The pliable insert 72 is formed 25 so that it fits inside the hole in a clearance fit. 26 Ideally, once inserted there should be essentially 27 no gap between the insert 72 and the wall 65 of the 28 29 bone plate 60. 30 The pliable insert 72 can typically be squeezed into 31

the hole 64'. For example, the material of the

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pliable insert 72 could be chosen such that a slight 1 heating of the pliable insert 72 would make the 2 insert 72 compressible to fit in the hole 64'. 3 Other embodiments can be envisaged where the pliable 4 insert 72 is formed in the hole 64' by melting the 5 pliable material and allowing it to set within the 6 7 hole. 8 Once inserted, the insert 72 is retained in the hole 9 64' by the hourglass-shape of the walls 65. 10 insert 72 would typically be inserted into the hole 11 64' before surgery, but in certain circumstances the 12 insert 72 can be inserted peroperatively. 13 14 The interior surfaces of the other holes 62, 64 in 15 the bone plate 60 have a similar shape. 16 17 Fig 15 shows the hole 64' of the bone plate 60 18 having an alternative embodiment of pliable insert 19 76, typically made from a resilient material such as 20 a resilient plastics material or a rubber. 21 lower end 78 (defined with reference to the bone 22 plate) of the insert 76 has wedge-shaped slits 80 23 cut between adjacent legs. The slits 80 are aligned 24 parallel to the axis X, with the tip of each cut-out 25 wedge at the upper end of each slit 80, giving a 26 pleated effect. The legs of the insert 76 do not 27 extend all of the way to the lower surface 68 of the 28 plate 60 in this embodiment. The upper end 77 of 29 the insert 76 mirrors the shape of the upper parts 30 of the walls 65. 31

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1 The insert 76 is engaged in the hole by squeezing the legs at the lower end 78 of the insert 76 so 2 3 that the slits 80 are compressed together, the legs are parallel to one another, and the lower end 78 of 4 5 the insert 76 is squeezed into a generally 6 cylindrical arrangement that can pass the apex 70 of 7 the walls 65. Thus, the insert 76 can be squeezed into the hole 64' and once in position, the 8 9 resilience of the pliable insert 76 will cause the 10 slits 80 to assume their original wedge-like shapes, splaying the legs outwards, and the lower end of the 11 12 insert 76 will be trapped below the apex 70, thus 13 retaining the insert 76 in the hole 64', as shown in 14 Fig 15. 15 16 This embodiment provides the advantage that the 17 insert 76 can be inserted into the hole 64' without 18 any external heating or special application of extra 19 force, so the insert 76 can easily be inserted into 20 any suitable hole at any time before or during the 21 operation with an easy press-fit. Driving a fixing 22 device such as a screw through the insert 76 will 23 keep the legs splayed and securely anchor the insert 24 76 within the hole 64'. 25 26 Fig 16 shows the bone plate 60 and insert 72 of Fig 27 14, with a screw 82 screwed into the insert 72. 28 screw 82 has a head 84 and a shaft 86, both of which 29 are threaded. The screw 82 is inserted far enough into the insert 72 such that the head 84 is threaded 30 into the insert 72 in addition to the shaft 86. 31 The 32 threads of the screw 82 cut into the bone (not

1	shown) and the screw 82 acts as a fixing device to
2	attach the bone plate 60 to the bone.
3	
4	The axis of the screw 82 is shown by the line Y in
5	Fig 16; it is not co-axial with the axis X of the
6	hole 64' but is inclined relative thereto. The
7	invention provides the significant advantage over
8	conventional bone fixing devices that it allows the
9	selection of the angle of insertion of the screw 82,
10	without the surgeon being forced to change the
11	attitude or orientation of the hole or the bone
12	plate 60. Examples of several possible screw
13	orientations are shown as dotted lines S, T, U, V in
14	Figs 14 and 15. The screw position/angle is
15	typically chosen prior to the insertion of the screw
16	82. The angle of screw insertion would typically be
17	influenced by the diameter of the leading thread of
18	screw, the core diameter of the screw, and the shape
19	and diameter of the screw head.
20	
21	The insert 76 of the Fig 15 embodiment can receive a
22	screw in just the same way as shown in Fig 16 for
23	the insert 72.
24	
25	The inserts 72, 76 could either be formed with one
26	or more predrilled holes for insertion of screws, or
27	alternatively, the inserts 72, 76 could be solid and
28	the screw holes could be drilled according to the
29	surgeon's requirements or judgement during the
30	operation. An advantage of pre-drilled holes is
31	that this eliminates the possibility that the
32	surgeon might drill through the insert and into the

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bone plate. On the other hand, if a hole is drilled 1 in a solid insert during the operation, the surgeon 2 has complete freedom of choice of hole angle. 3 4 The embodiments described in Figs 14 to 16 are 5 adapted for circular holes and have axial symmetry, 6 so that the inserts 72, 76 can be rotated in their 7 respective holes. Rotation of the insert 72, 76 8 sweeps the angle of the hole around in an arc, 9 allowing the surgeon even more freedom of choice to 10 insert the screw 82 at the required angle, or in the 11 12 required direction. 13 Fig 17 shows a yet further alternative embodiment, 14 wherein a bone plate 90 has an upper surface 92 and 15 a lower surface 94. The bone plate 90 has holes 96 16 (only one shown) having tapered walls. The hole 96 17 is frusto-conical, the narrower end being at the 18 lower surface 94 and the wider end being at the 19 upper surface 92. Thus, the walls of the hole 96 20 are inclined radially inwards from the upper surface 21 92 to the lower surface 94. Unlike the embodiments 22 of Figs 11 to 16, there is no apex in the surface of 23 the walls, the inclination being typically 24 continuous between the upper and lower surfaces 92, 25 94, although an annular stop could be formed at the 26 lower surface 94 if desired (not shown). 27 28 The hole 96 has a pliable insert 98 inserted 29 The insert 98 is also in the form of a 30 therein. trapezium, being dimensioned to fit the shape of the 31 hole 96, so that the insert 98 fits in and fills the 32

hole 96 as shown in Fig 17. The angle of

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inclination of the sides is exaggerated in figure 2 17, and in practice any significant inclination of 3 the walls is useful, as it permits the insert to 4 enter and leave the hole only through the wider 5 aperture of the top surface 92. 6 7 In certain simple embodiments of this version, the 8 sidewalls (i.e. not the upper and lower surfaces) of 9 both of the insert 98 (typically) and the hole 96 10 can be plain, but in the more advanced embodiment 11 chown the sidewall of at least the hole 96 is screw 12 threaded in order to grip the insert 98 more 13 securely. The outer wall of the insert can also be 14 threaded as shown in this embodiment, but in other 15 versions, it is sufficient for the thread to be cut 16 into the insert 98 by the thread on the hole 96 17 during insertion of the insert 98 into the hole 96. 18 In this example, the coupled threads are designated 19 100 in the drawing. Therefore, this embodiment 20 provides a pliable insert that can be screwed into a 21 bone plate by engaging the threads of the plate 22 aperture and the insert. The insert 98 can be 23 screwed into holes in conventional bone plates where 24 required in order to fix the insert more securely to 25 the plate. Thus, when the screw or other bone 26 fixing device is driven through the insert 98, the 27 consequent deformation of the insert 98 pushes the 28 plastic of the insert even more firmly into the 29 threads on the inner surface of the hole 96, thereby 30 reducing the possibility of the insert allowing any 31

23

play of the plate and fixing after the two are 1 2 finally connected. 3 As with previous embodiments, the screws or other 4 5 fixings can be driven through the solid plug of the insert 98 or alternatively the insert 98 can have 6 pre-drilled holes to quide insertion of the fixings. 7 Naturally, with pre-drilled holes in the insert 98, 8 the insert 98 can be rotated to select a suitable 9 path for the fixing into the bone. This feature 10 can be especially useful if part of the bone is 11 comminuted, the bone portions in these parts being 12 very tiny, and where especially accurate selection 13 of the angle of insertion of the screws is required. 14 In some embodiments, some of the holes in the bone 15 plate could be used with screws directly, and the 16 holes relating to the comminuted parts of the 17 fracture could be filled with an insert according to 18 the invention. 19 20 Fig 18 shows the Fig 17 insert 98 with a screw 82 21 22 driven therethrough. 23 The invention allows the use of smaller screws, as 24 in this invention, the size of the screw is not 25 defined by the size of the hole in the bone plate; 26 any size of screw smaller than the hole can be 27 chosen. Again, this may be particularly useful for 28 comminuted fractures. 29 30 If the conventional bone plate has holes with 31

parallel walls, a correspondingly parallel-walled

insert could be provided. Therefore, this invention

2 also provides embodiments which can be used in

3 conjunction with conventional bone plates/

4 intramedullary nails, as and where required, to give

24

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5 the advantage of being able to select the angle of

6 insertion of the hole and the required screw size.

7

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8 It should be noted that the non-parallel sided

9 designs of insert and bone fixture apparatus in the

10 embodiments of Figs 11 to 17 could equally be

11 applied to the intra-medullary nail embodiments;

these do not necessarily relate only to bone plates.

13

14 It should also be noted that in the embodiments of

15 Fig 17 and 18 it is not necessary for the insert 98

to be threaded, and the thread can be cut into the

17 insert 98 by the act of screwing a blank insert 98

18 into the hole.

19

20 Modifications and improvements can be incorporated

21 without departing from the scope of the invention.

22 For example, the bone fixture apparatus may be a

23 bone plate, a fracture brace or any other kind of

24 bone fixture apparatus; the invention does not

25 necessarily relate to intra-medullary nails.

26

Other types of pliable material may be used beyond

28 the types specifically mentioned above.

29

30 The bone fixture apparatus does not necessarily

31 include holes. For example, the pliable material

32 could be bonded to the bone fixture apparatus and a

25

1 fixing device could be engaged with the pliable

2 material alone.

·

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1 <u>Claims</u>

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2

- 3 1. A bone fixture apparatus having a pliable
- 4 material for engaging a fixing device.

5

- 6 2. A bone fixture apparatus as claimed in claim 1,
- 7 wherein the pliable material is deformable.

8

- 9 3. A bone fixture apparatus as claimed in claim 1
- or claim 2, wherein the pliable material comprises
- 11 an insert.

12

- 13 4. A bone fixture apparatus as claimed in any
- 14 preceding claim, wherein the form of the pliable
- 15 material is selected from the group consisting of a
- 16 hollow sleeve, at least one ring, a plug, a coating
- 17 and a liner.

18

- 19 5. A bone fixture apparatus as claimed in any
- 20 preceding claim, wherein the pliable material is
- 21 received in a threaded aperture in the apparatus.

22

- 23 6. A bone fixture apparatus as claimed in any
- 24 preceding claim, wherein the pliable material is
- 25 settable.

26

- 7. A bone fixture apparatus as claimed in any
- 28 preceding claim, wherein the pliable material is
- 29 expandable.

- 31 8. A bone fixture apparatus as claimed in claim 7,
- 32 wherein the pliable material is self-expanding.

27

2 9. A bone fixture apparatus as claimed in any

3 preceding claim, wherein the pliable material lines

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at least a part of the inside of the bone fixture

5 apparatus.

6

4

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7 10. A bone fixture apparatus as claimed in any

8 preceding claim, wherein the pliable material is

9 located within a passage of the bone fixture

10 apparatus.

11

12 11. A bone fixture apparatus as claimed in claim

13 10, wherein the pliable material fills the

14 transverse cross-sectional area of the passage.

15

16 12. A bone fixture apparatus as claimed in any

17 preceding claim, wherein the bone fixture apparatus

18 has at least one hole to receive a respective fixing

19 device and wherein the pliable material is located

20 in a region of the hole.

21

22 13. A bone fixture apparatus as claimed in claim

23 12, wherein the pliable material lines the inside of

24 the hole.

25

26 14. A bone fixture apparatus as claimed in claim 12

or claim 13, having a cylindrical passage through

28 the bone fixture apparatus terminating in a

29 respective hole at each end of the passage.

30

31 15. A bone fixture apparatus as claimed in claim

32 14, wherein the pliable material is located at each

28

- end of the passage, around the inside surface of the
- 2 passage.

3

- 4 16. A bone fixture apparatus as claimed in claim 14
- 5 or claim 15, wherein the entire passage is filled
- 6 with pliable material.

7

- 8 17. A bone fixture apparatus as claimed in claim 12
- 9 or claim 13, wherein the bone fixture apparatus is
- 10 hollow and the pliable material is in the form of a
- 11 sleeve or cylinder that spans the gap between holes
- in opposite sides of the bone fixture apparatus.

13

- 14 18. A bone fixture apparatus as claimed in any of
- 15 claims 12 to 17, wherein the hole is tapered.

16

- 17 19. A bone fixture apparatus as claimed in any of
- 18 claims 12 to 18, wherein the pliable material is in
- 19 the form of an insert which fills the hole.

20

- 21 20. A bone fixture apparatus as claimed in claim
- 22 19 when dependent on claim 18, wherein the insert
- 23 tapers to match the shape of the hole.

24

- 25 21. A bone fixture apparatus as claimed in claim 19
- or claim 20, wherein the hole and the insert are
- 27 frusto-conical.

- 29 22. A bone fixture apparatus as claimed in any of
- 30 claims 19 to 21, wherein the insert has a
- 31 compressible portion, which can be compressed to fit
- 32 through a narrow section of the hole.

29

1

2 23. A bone fixture apparatus as claimed in claim

3 22, wherein the compressible portion has slits.

4

5 24. A bone fixture apparatus as claimed in claim 22

or claim 23, wherein the compressible portion is

7 adapted to splay outwards to retain the insert in

8 the hole after insertion.

9

10 25. A bone fixture apparatus as claimed in any of

11 claims 19 to 24, wherein the insert is rotatable in

12 the hole.

13

14 26. A bone fixture apparatus as claimed in any of

15 claims 19 to 25, wherein the hole is provided with

16 internal screw threads.

17

18 27. A bone fixture apparatus as claimed in claim

19 26, wherein the insert has external screw threads to

20 engage the internal threads on the hole, such that

21 the insert can be screwed into the hole.

22

23 28. A bone fixture apparatus as claimed in any of

24 claims 19 to 27, wherein the insert has an aperture

25 therethrough to receive a fixing device.

26

27 29. A bone fixture apparatus as claimed in any

28 preceding claim, wherein the pliable material is

29 contained within a containment area of the bone

30 fixture apparatus.

30

1 30. A bone fixture apparatus as claimed in any

2 preceding claim, wherein the pliable material is

3 fixed to the bone fixture apparatus.

4

5 31. A bone fixture apparatus as claimed in any

6 preceding claim, wherein the pliable material is

7 selected from the group consisting of metals and

8 polymers.

9

10 32. A bone fixture apparatus as claimed in any

11 preceding claim, wherein the pliable material is

12 selected from the group consisting of a plastics

material, a carbon complex, polyethylene, nylon, and

14 collagen and polypeptide constructs.

15

16 33. A bone fixture apparatus as claimed in any

17 preceding claim, wherein the pliable material is

18 biodegradable or bioabsorbable.

19

20 34. A bone fixture apparatus as claimed in any

21 preceding claim, wherein the bone fixture apparatus

22 comprises an intra-medullary nail.

23

24 35. A bone fixture apparatus as claimed in any of

25 claims 1 to 33, wherein the bone fixture apparatus

26 comprises a bone plate.

27

28 36. A method of supporting a fractured bone, the

29 method comprising the steps of: attaching a bone

30 fixture apparatus to the bone and engaging at least

31 one fixing device with the bone, wherein the bone

32 fixture apparatus is provided with a pliable

31

1 material and the fixing device is engaged with the

2 pliable material.

3

4 37. A method as claimed in claim 36, wherein the

5 fixing device is threaded, and wherein on insertion,

6 the fixing device cuts threads in the pliable

7 material to hold the fixing device relative to the

8 pliable material.

9

10 38. A method as claimed in claim 36 or claim 37,

11 wherein the insertion of the fixing device displaces

12 some of the pliable material against the inside

13 surface of the bone fixture apparatus.

14

15 39. A method as claimed in any of claims 36 to 38,

wherein the pliable material is expandable upon

17 application of pressure and the insertion of the

18 fixing device causes the pliable material to expand.

19

20 40. A method as claimed in any of claims 36 to 39,

21 wherein the pliable material is contained within a

22 containment area in the bone fixture apparatus, and

when the fixing device is inserted, the pliable

24 material is displaced against the walls of the

25 containment area.

26

27 41. A method as claimed in any of claims 36 to 40,

28 wherein the fixing device is inserted through the

29 bone and through at least one hole in the bone

30 fixture apparatus.

32

1 42. A method as claimed in claim 41, wherein the

2 pliable material lines the hole in the bone fixture

3 apparatus.

4

5 43. A method as claimed in claim 41 or claim 42,

6 wherein the pliable material is in the form of an

7 insert which fills the hole in the bone fixture

8 apparatus.

9

10 44. A method as claimed in claim 43, wherein the

11 hole has internal threads, and the method includes

12 the step of screwing the insert into the hole.

13

14 45. A method as claimed in claim 44, wherein the

15 insert has external threads that engage with the

16 threads on the hole.

17

18 46. A method as claimed in any of claims 43 to 45,

19 wherein the insert is solid and an aperture is

20 drilled in the insert during surgery.

21

22 47. A method as claimed in any of claims 43 to 45,

23 wherein the insert has a predrilled aperture, which,

24 in use, is inclined relative to the hole axis, and

25 the method includes the step of rotating the insert

26 to select the orientation of the aperture.

27

28 48. A method as claimed in any of claims 43 to 47,

29 wherein the hole has an internal throat and the

insert has a compressible portion, and the method

31 includes the step of compressing the portion to fit

33

- 1 the insert at least partially through the throat of
- 2 the hole.

3

- 4 49. A method as claimed in claim 48, wherein the
- 5 compressible portion has legs which can be pushed
- 6 together to compress the portion to fit the insert
- 7 through the throat of the hole and which splay apart
- 8 when in position in the hole to grip the hole.

9

- 10 50. The use of a pliable material in co-operation
- 11 with a bone fixture apparatus in a method of
- 12 supporting a bone fracture.

13

- 14 51. A pliable insert for engaging a fixing device
- 15 for a bone fixture apparatus.

16

- 17 52. A pliable insert as claimed in claim 51,
- 18 wherein the insert is deformable.

19

- 20 53. A pliable insert as claimed in claim 51 or
- 21 claim 52, wherein the insert has external screw
- 22 threads.

23

- 24 54. A pliable insert as claimed in any of claims 51
- 25 to 53, wherein the insert is settable.

26

- 27 55. A pliable insert as claimed in any of claims 51
- 28 to 54, wherein the insert is expandable.

29

- 30 56. A pliable insert as claimed in claim 55,
- 31 wherein the insert is self-expanding.

1 57. A pliable insert as claimed in any of claims 50

34

2 to 56, wherein the insert tapers bi-directionally to

3 form a waist.

4

5 58. A pliable insert as claimed in any of claims 51

6 to 57, wherein the insert has a compressible end.

7

8 59. A pliable insert as claimed in claim 58,

9 wherein the compressible end has legs divided by

10 slits, and wherein the legs can be pushed together

11 to compress the end.

12

13 60. A pliable insert as claimed in claim 59,

14 wherein the legs of the insert are adapted to splay

15 outwards on the engagement of a fixing device with

16 the insert.

17

18 61. A bone fixture apparatus as claimed in any of

19 claims 51 to 60, wherein the insert has an aperture

20 therethrough to receive a fixing device.

21

22 62. A pliable insert as claimed in any of claims 51

23 to 61, wherein the insert comprises a material

24 selected from the group consisting of metals and

25 polymers.

26

27 63. A pliable insert as claimed in any of claims 51

28 to 62, wherein the insert comprises a material

29 selected from the group consisting of a plastics

30 material, a carbon complex, polyethylene, nylon, and

31 collagen and polypeptide constructs.

35

1 64. A pliable insert as claimed in any of claims 51

2 to 63, wherein the insert is biodegradable.

3

4 65. A bone fixing apparatus having at least one

5 hole, wherein the hole is provided with a tapered

6 inner surface.

7

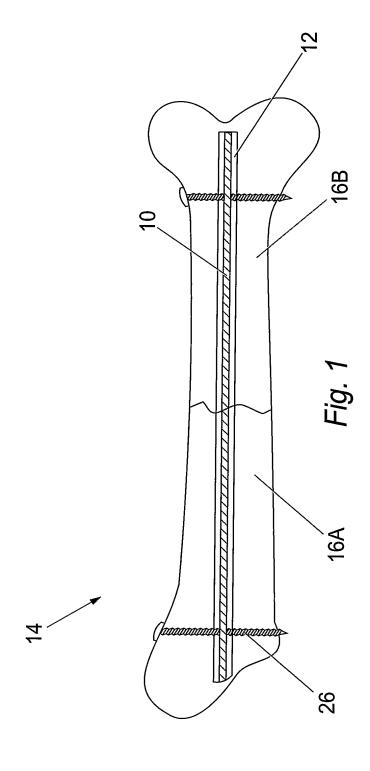
8 66. A bone fixing apparatus as claimed in claim 65,

9 wherein the hole is bi-directionally tapered to form

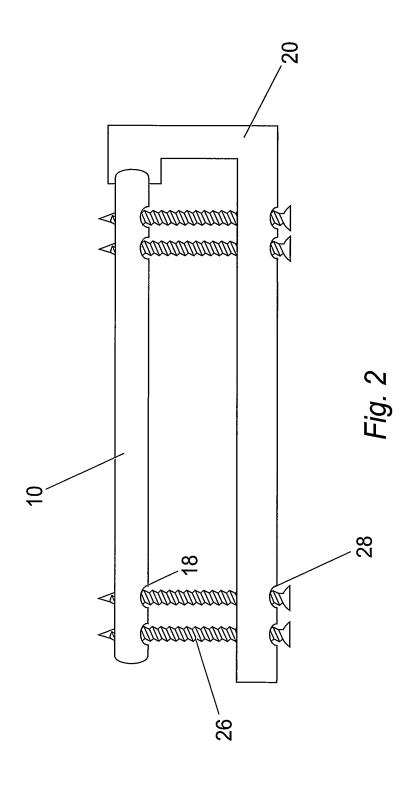
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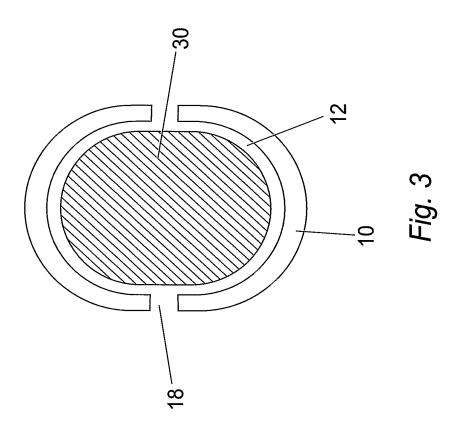
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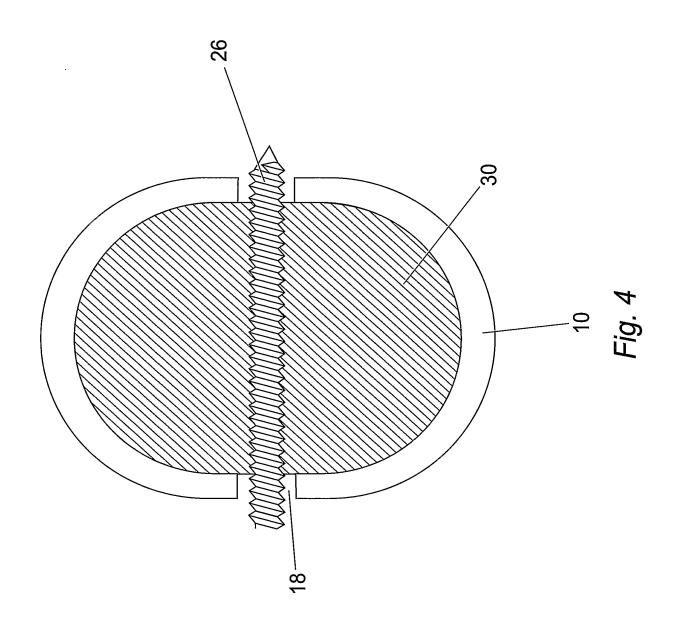
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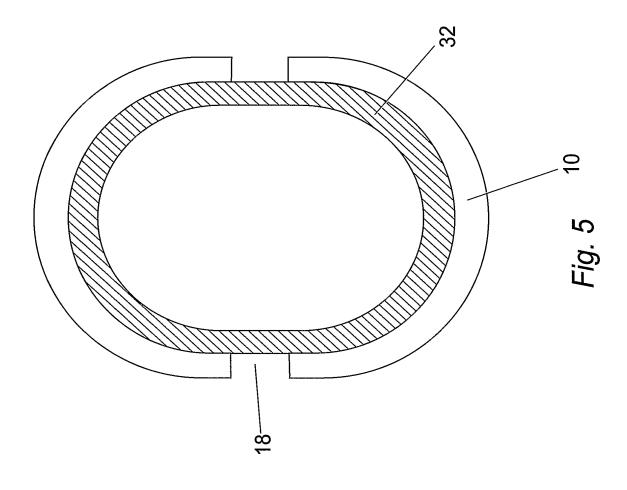


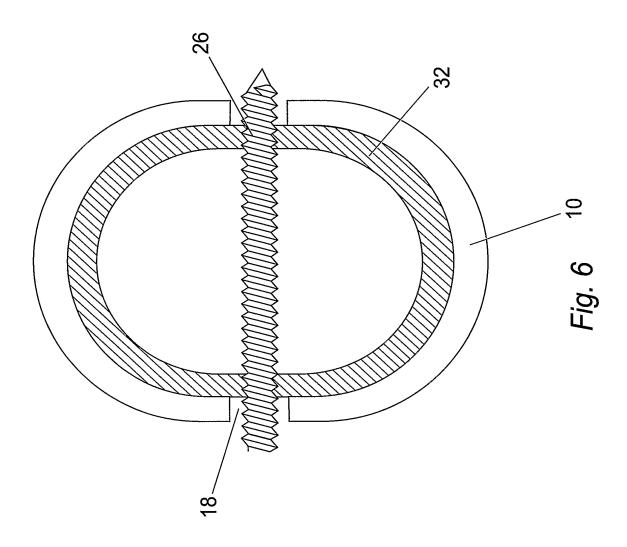
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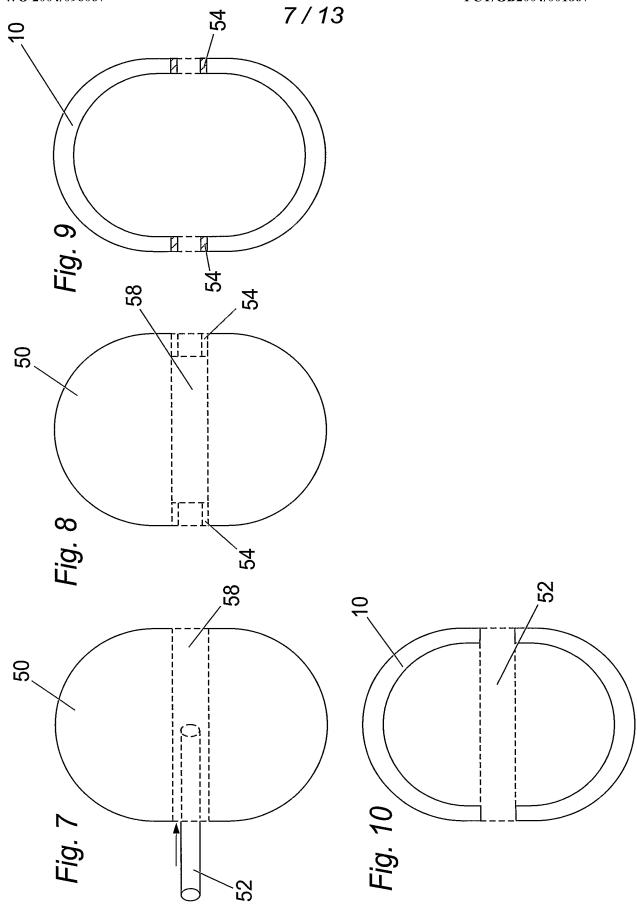




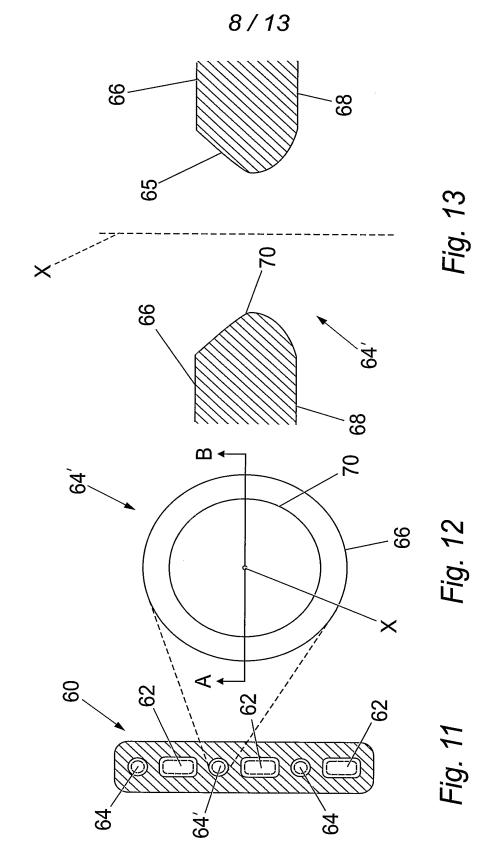




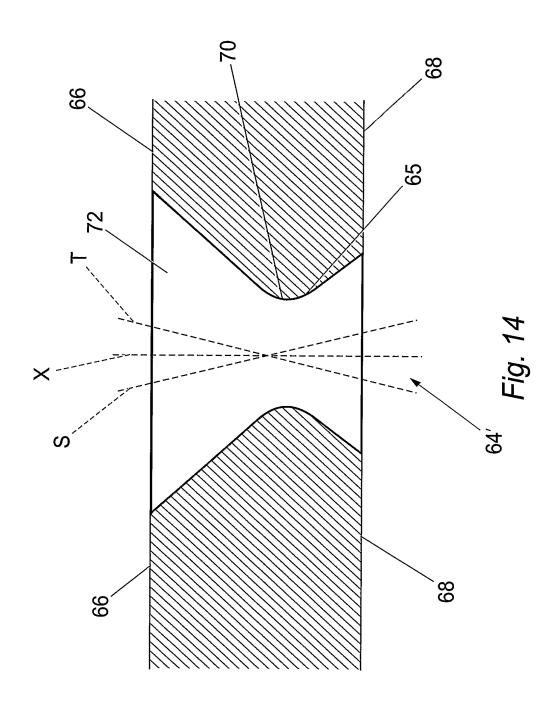


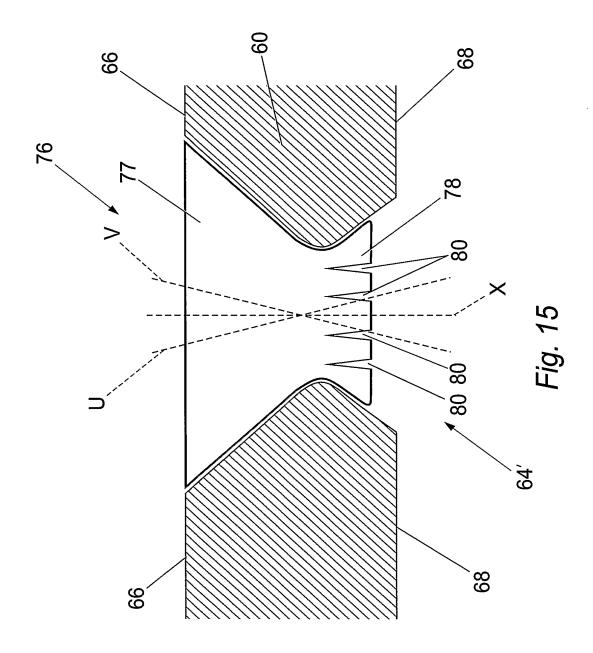


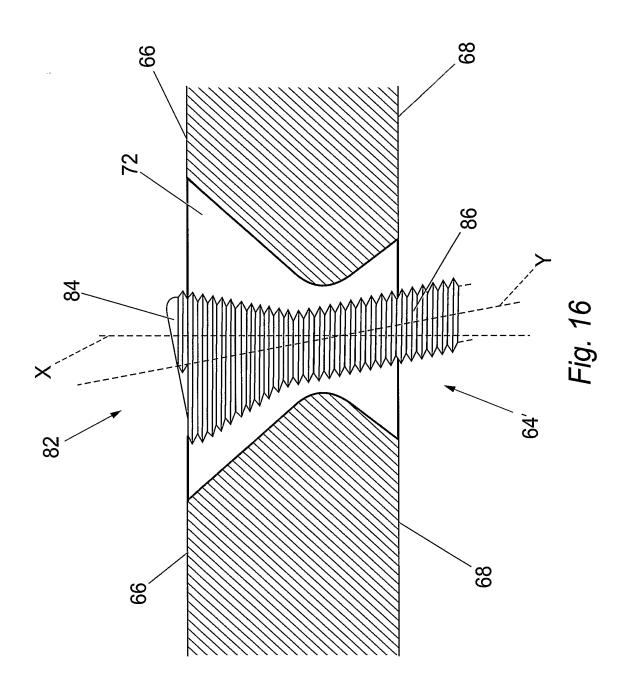
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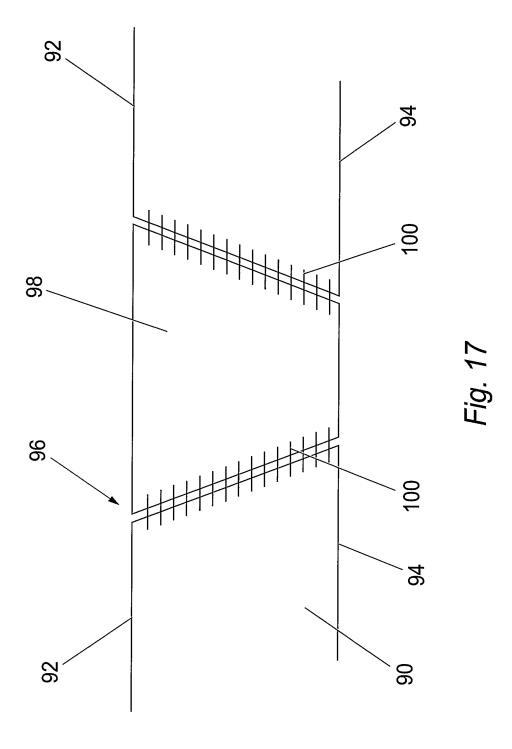


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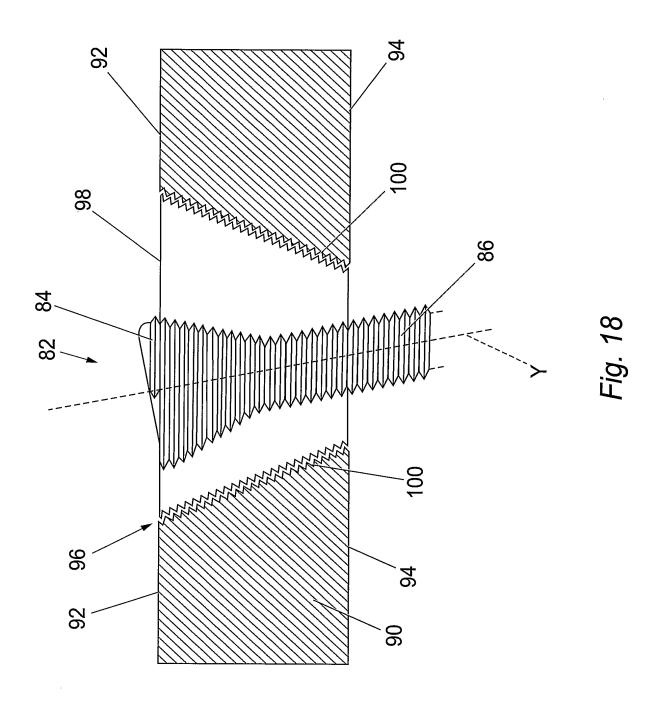








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